

Claims:

1. A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising:

a sheet having at least one opening therethrough and a plurality of blades extending downward therefrom, at least one of the plurality of blades having an anchor for anchoring the device to the body surface.

2. The device of Claim 1 wherein the anchor is selected from the group consisting:

- (i) a projection extending out from the at least one blade;
- (ii) a barb;
- (iii) at least one opening extending through the at least one blade;
- (iv) an adhesive on a body contacting surface of the sheet and on at least one surface of at least one of the plurality of blades;
- (v) each of the blades having an axis, the blades being oriented so that the blade axes are substantially parallel and the axes form an angle of about 1° to about 89° relative to the sheet;
- (vi) each one of the plurality of blades defines essentially a plane and wherein the anchor comprises a portion of the plurality of blades being oriented at an angle of about 90° with respect to a remaining portion of the plurality of blades; and
- (vii) each one of the plurality of blades defines essentially a plane and wherein the anchor comprises a portion of the plurality of blades being oriented at an angle within a range of about 1° to about 89° with respect to a remaining portion of the plurality of blades.

3. The device of Claim 2, wherein the projection extends out from a plane defined by the at least one blade.

1 4. The device of Claim 3, wherein the projection is a prong.

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3 5. The device of Claim 2, wherein the projection is integral with an
4 edge of the at least one blade and in a plane defined by the at least one
5 blade.

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7 6. The device of Claim 1, further comprising a therapeutic agent
8 delivery device connected to the piercing device and positioned to deliver a
9 therapeutic agent through the opening to the body surface, the agent delivery
10 device being selected from the group consisting of an electrotransport device,
11 a passive diffusion device, an osmotic device, and a pressure driven device.

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13 7. The device of Claim 6, wherein the agent comprises a polypeptide
14 or protein.

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16 8. The device of Claim 1, further comprising a sampling device
17 connected to the piercing device and positioned to sample a substance from
18 the body surface through the opening, the sampling device being selected
19 from the group consisting of a reverse electrotransport device, a passive
20 diffusion device, an osmotic device, and a negative pressure driven device.

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22 9. The device of Claim 8, wherein the sampled substance is selected
23 from the group consisting of body electrolytes, illicit drugs and glucose.

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25 10. The device of Claim 1, wherein a portion of the plurality of blades
26 are located along a periphery of an opening through the sheet.

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28 11. The device of Claim 1, wherein a portion of the plurality of blades
29 are located along a periphery of a plurality of openings through the sheet.

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1 12. The device of Claim 11, further comprising a plurality of second
2 openings through the sheet being spaced between the plurality of openings.

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4 13. The device of Claim 1, wherein the device has about 600 to about
5 1000 blades/cm².

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7 14. The device of Claim 1, wherein the device has at least about 800
8 blades/cm²

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10 15. The device of Claim 1, wherein at least a portion of the plurality of
11 blades have a length sufficient to pierce the stratum corneum of the body
12 surface to a depth of at least about 25 μ m.

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14 16. The device of Claim 1, wherein each of the plurality of blades is
15 oriented approximately perpendicular to the sheet.

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17 17. The device of Claim 1, wherein each of the plurality of blades is
18 oriented at an angle in the range of about 1° to about 89° to the sheet.

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20 18. The device of Claim 1, wherein each of the plurality of blades is
21 oriented at an angle in the range of about 10° to about 60° to the sheet.

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23 19. The device of Claim 1, wherein at least a portion of the plurality of
24 blades have a thickness in the range of about 7 μ m to about 100 μ m.

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26 20. The device of Claim 1, wherein at least a portion of the plurality of
27 blades have a thickness in the range of about 25 μ m to about 50 μ m.
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1 21. The device of Claim 1, wherein the plurality of blades is composed
2 of a material selected from the group consisting of metals, metal alloys,
3 glasses, ceramics and rigid polymers.

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5 22. The device of Claim 1, wherein the sheet and the plurality of
6 blades are substantially impermeable to the passage of the agent.

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8 23. The device of Claim 1, wherein the plurality of blades are thinner
9 than the sheet.

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11 24. A device for piercing the stratum corneum of a body surface to
12 form pathways through which an agent can be introduced or withdrawn,
13 comprising:

14 a sheet having a plurality of openings therethrough, at least one of
15 said openings having a plurality of blades located along a periphery thereof
16 and extending downward from the sheet, and an anchor for anchoring the
17 device to the body surface.

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19 25. The device of Claim 24, wherein the anchor is selected from the
20 group consisting:

- 21 (i) a projection extending out from at least one blade;
22 (ii) a barb on a blade;
23 (iii) at least one opening extending through at least one blade;
24 (iv) an adhesive on a body contacting surface of the sheet and on at
25 least the plurality of blades;
26 (v) a portion of the plurality of blades being oriented at an angle of
27 about 90° with respect to a remaining portion of the plurality of blades; and
28 (vi) each one of the plurality of blades defines essentially a plane and
29 wherein the anchor comprises a portion of the plurality of blades being

1 oriented at an angle within a range of about 1° to about 89° with respect to a
2 remaining portion of the plurality of blades.

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4 26. The device of Claim 25, wherein the projection extends out from a
5 plane defined by at least one blade.

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7 27. The device of Claim 26, wherein the projection is a prong.

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9 28. The device of Claim 25, wherein the projection is integral with an
10 edge of the at least one blade and in a plane defined by the at least one
11 blade.

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13 29. The device of Claim 24, wherein the anchor comprises a plurality
14 of openings extending through at least one blade.

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16 30. The device of Claim 24, further comprising a therapeutic agent
17 delivery device connected to the piercing device and positioned to deliver a
18 therapeutic agent through the opening to the body surface, the agent delivery
19 device being selected from the group consisting of an electrotransport device,
20 a passive diffusion device, an osmotic device, and a pressure driven device.

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22 31. The device of Claim 30, wherein the agent comprises a
23 polypeptide or protein.

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25 32. The device of Claim 24, further comprising a sampling device
26 connected to the piercing device and positioned to sample a substance from
27 the body surface through the openings, the sampling device selected from
28 the group consisting of a reverse electrotransport device, a passive device,
29 an osmotic device, and a negative pressure driven device.
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1 33. The device of Claim 32, wherein the sampled substance is
2 selected from the group consisting of body electrolytes, illicit drugs and
3 glucose.

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5 34. The device of Claim 24, further comprising a plurality of second
6 openings through the sheet being spaced between the plurality of openings.

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8 35. The device of Claim 24, wherein the device has about 600 to
9 about 1000 blades/cm².

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11 36. The device of Claim 24, wherein the device has at least about
12 800 blades/cm².

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14 37. The device of Claim 24, wherein at least a portion of the plurality
15 of blades have a length sufficient to pierce the stratum corneum of the body
16 surface to a depth of at least about 25 μ m.

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18 38. The device of Claim 24, wherein each of the plurality of blades is
19 oriented approximately perpendicular to the sheet.

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21 39. The device of Claim 24, wherein each of the plurality of blades is
22 oriented at an angle in the range of about 1° to about 89° to the sheet.

23
24 40. The device of Claim 24, wherein each of the plurality of blades is
25 oriented at an angle in the range of about 10° to about 60° to the sheet.

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27 41. The device of Claim 24, wherein the plurality of blades have a
28 thickness in the range of about 7 μ m to about 100 μ m.
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1 42. The device of Claim 24, wherein the plurality of blades have a
2 thickness in the range of about 25 micrometers to about 50 micrometers.

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4 43. The device of Claim 24, wherein each of the plurality of blades are
5 composed of a material selected from the group consisting of metals, metal
6 alloys, glasses, ceramics and rigid polymers.

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8 44. The device of Claim 24, wherein the sheet and the plurality of
9 blades are substantially impermeable to the passage of the agent.

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11 45. The device of Claim 24, wherein the plurality of blades are thinner
12 than the sheet.

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14 46. A method for producing a device for piercing the stratum corneum
15 of a body surface, the method comprising:

16 applying a layer of photo-resist to a first side of a sheet;

17 exposing the layer of photo-resist through a mask pattern for
18 producing a plurality of blades,

19 etching exposed portions of the photo-resist and the sheet to produce
20 the plurality of blades and openings through the sheet;

21 punching the plurality of blades through the openings such that the
22 plurality of blades extend downward from the sheet; and

23 incorporating the device for piercing the stratum corneum into a
24 delivery device or sampling device.

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26 47. The method of Claim 46, wherein the photo-resist is a resist
27 selected from the group consisting of wet resist and dry resist.

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29 48. The method of Claim 46, wherein the etching step comprises
30 spray etching.

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49. The method of Claim 46, wherein the punching step comprises:

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placing the sheet on a die having a plurality of openings corresponding

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to the plurality of blades and openings of the sheet; and

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bending the plurality of blades through the openings to be substantially

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perpendicular to the sheet with a punch having a plurality of protrusions

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corresponding to the plurality of openings in the die and the plurality of

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openings of the sheet.

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50. A method of transdermally sampling an agent, comprising:

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a. placing a device on a body surface through which the agent is to

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be withdrawn, the device including a sheet having at least one opening

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therethrough and a plurality of blades extending downward therefrom

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whereby agent transmitting pathways are formed through the stratum

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corneum at the body surface, and a reservoir in agent-transmitting relation

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with the opening;

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b. withdrawing the agent through the pathways and said opening; and

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c. collecting the agent in the reservoir.

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51. The method of Claim 50, wherein the sampled agent is selected

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from the group consisting of body analytes, electrolytes, blood gases, illicit

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drugs, licit drugs and glucose.

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52. The method of Claim 50, further comprising:

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connecting a sampling device to a side opposite of a side of the sheet

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having the blades extending downward therefrom, the sampling device being

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selected from the group consisting of a reverse electrotransport sampling

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device, a passive sampling device, an osmotic sampling device, and a

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negative pressure driven sampling device.

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